IHE統合プロファイル「可搬型医用画像」

IHE:PDI(Portable Data for Imaging）Integration Profile

本書はIHEが定める放射線部門（Radiology）のテクニカルフレームワークの内媒体による画像を含む診療情報を交換するための統合プロファイルについて、“IHE Technical Framework，Vol.I Integration Profilesの１，２，１５章およびVol.III Transactions (Continued) Rev.8.0”から４章のPDIに関する部分を抜粋しまとめたものである。IHEテクニカルフレームワークの全体像が分かるように、IntroductionやProfilesなどの記述についてはそのまま残した。また、本書の出典元である上述のテクニカルフレームワークの記述部分が分かるように章、節などの番号はそのままの形で利用している。必要があればRadiology Domain IHE Technical Framework を参照いただきたい。参照先は以下である。

http://www.ihe.net/Technical_Framework/index.cfm#radiology

Radiology Technical Framework

Revision 8.0

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Final Text Version

1 Introduction

Integrating the Healthcare Enterprise (IHE) is an initiative designed to stimulate the integration of the information systems that support modern healthcare institutions. Its fundamental objective is to ensure that in the care of patients all required information for medical decisions is both correct and available to healthcare professionals. The IHE initiative is both a process and a forum for encouraging integration efforts. It defines a technical framework for the implementation of established messaging standards to achieve specific clinical goals. It includes a rigorous testing process for the implementation of this framework. And it organizes educational sessions and exhibits at major meetings of medical professionals to demonstrate the benefits of this framework and encourage its adoption by industry and users.

The approach employed in the IHE initiative is not to define new integration standards, but rather to support the use of existing standards◎initially DICOM and HL7, but potentially others, as appropriate in their respective domains◎in an integrated manner, defining configuration choices when necessary. When clarifications or extensions to existing standards are necessary, IHE refers recommendations to the relevant standards bodies.

This initiative has numerous sponsors and supporting organizations in different medical specialty domains and geographical regions. In North America the primary sponsors are the Healthcare Information and Management Systems Society (HIMSS) and the Radiological Society of North America (RSNA). The American College of Cardiology (ACC) and Laboratory Healthcare Partnership (LHCP) are currently supporting exploratory IHE activities in their respective domains. IHE Europe (IHE-EUR) is supported by a large coalition of organizations including the European Association of Radiology (EAR) and European Congress of Radiologists (ECR), the Coordination Committee of the Radiological and Electromedical Industries (COCIR), Deutsche Röntgengesellschaft (DRG), the EuroPACS Association, Groupement pour la Modernisation du Système d'Information Hospitalier (GMSIH), Société Francaise de Radiologie (SFR), and Società Italiana di Radiologia Medica (SIRM). In Japan IHE-J is sponsored by the Ministry of Economy, Trade, and Industry (METI); the Ministry of Health, Labor, and Welfare; and MEDIS-DC; cooperating organizations include the Japan Industries Association of Radiological Systems (JIRA), the Japan Association of Healthcare Information Systems Industry (JAHIS), Japan Radiological Society (JRS), Japan Society of Radiological Technology (JSRT), and the Japan Association of Medical Informatics (JAMI). Other organizations representing healthcare professionals are invited to join in the expansion of the IHE process across disciplinary and

geographic boundaries.

1.1 Overview of Technical Framework

This document, the IHE Technical Framework, defines specific implementations of established standards to achieve integration goals that promote appropriate sharing of medical information to support optimal patient care. It is expanded annually, after a period of public review, and maintained regularly through the identification and correction of errata. The current version, rev. 8.0, specifies the IHE transactions defined and implemented as of April 2007. The latest version of the document is always available via the Internet at www.ihe.net/Technical_Framework/.

The IHE Technical Framework identifies a subset of the functional components of the healthcare enterprise, called IHE Actors, and specifies their interactions in terms of a set of coordinated, standards-based transactions. It describes this body of transactions in progressively greater depth. The present volume provides a high-level view of IHE functionality, showing the transactions organized into functional units called Integration Profiles that highlight their capacity to address specific clinical needs. The subsequent volumes, II and III, provide detailed technical descriptions of each IHE transaction.

The other domains within the IHE initiative also produce Technical Frameworks within their respective areas that together form the IHE Technical Framework. Currently, the following IHE Technical Framework(s) are available:

- IHE IT Infrastructure Technical Framework
- IHE Radiology Technical Framework

Where applicable, references are made to other technical frameworks. For the conventions on referencing other frameworks, see Section 1.6.4 within this volume.

1.2 Overview of Volume I

The remainder of section 1 further describes the general nature, purpose and function of the Technical Framework. Section 2 introduces the concept of IHE Integration Profiles that make up the Technical Framework.

Section 3 and the subsequent sections of this volume provide detailed documentation on each integration profile, including the clinical problem it is intended to address and the IHE Actors and transactions it comprises.

The appendices following the main body of the document provide detailed discussion of specific issues related to the integration profiles and a glossary of terms and acronyms used.

1.3 Audience

The intended audience of this document is:

- Technical staff of vendors participating in the IHE initiative
- IT departments of healthcare institutions
- Experts involved in standards development
- Anyone interested in the technical aspects of integrating healthcare information systems

1.4 Relationship to Standards

The IHE Technical Framework identifies functional components of a distributed healthcare environment (referred to as IHE Actors), solely from the point of view of their interactions in the healthcare enterprise. At its current level of development, it defines a coordinated set of transactions based on the HL7 and DICOM standards. As the scope of the IHE initiative expands, transactions based on other standards will be included as required.

In some cases, IHE recommends selection of specific options supported by these standards; however, IHE does not introduce technical choices that contradict conformance to these standards. If errors in or extensions to existing standards are identified, IHE's policy is to report them to the appropriate standards bodies for resolution within their conformance and standards evolution strategy.

IHE is therefore an implementation framework, not a standard. Referencing IHE as a standard is inappropriate. Conformance claims by product must still be made in direct reference to specific standards. In addition, vendors who have implemented IHE integration capabilities shall use an IHE Integration Statement to describe the conformance of their product to the specifications in the IHE Technical Framework. The purpose of an IHE Integration Statement is to communicate to the users of the corresponding product the IHE capabilities it has been designed to support. Vendors publishing IHE Integration Statements accept full responsibility for their content. By comparing the IHE Integration Statements from different implementations, a user familiar with the IHE concepts of Actors and Integration Profiles should be able to

determine whether and to what extent communications might be supported between products. See Appendix D for the format of such IHE Integration Statements. IHE encourages implementers to ensure that products implemented in accordance with the IHE Technical Framework also meet the full requirements of the standards underlying IHE, allowing the products to interact, although possibly at a lower level of integration, with products that have been implemented in conformance with those standards, but not in full accordance with the IHE Technical Framework.

1.5 Relationship to Real-world Architectures

The IHE Actors and transactions described in the IHE Technical Framework are abstractions of the real-world healthcare information system environment. While some of the transactions are traditionally performed by specific product categories (e.g. HIS, Electronic Patient Record, RIS, PACS, Clinical Information Systems or imaging modalities), the IHE Technical Framework intentionally avoids associating functions or actors with such product categories. For each actor, the IHE Technical Framework defines only those functions associated with integrating information systems. The IHE definition of an actor should therefore not be taken as the complete definition of any product that might implement it, nor should the framework itself be taken to comprehensively describe the architecture of a healthcare information system.
The reason for defining actors and transactions is to provide a basis for defining the interactions among functional components of the healthcare information system environment. In situations where a single physical product implements multiple functions, only the interfaces between the product and external functions in the environment are considered to be significant by the IHE initiative. Therefore, the IHE initiative takes no position as to the relative merits of an integrated environment based on a single, all-encompassing information system versus one based on multiple systems that together achieve the same end. To illustrate most dramatically the possibilities of the IHE Technical Framework, however, the IHE demonstrations emphasize the integration of multiple vendors' systems based on the IHE Technical Framework.

1.6 Conventions

This document has adopted the following conventions for representing the framework concepts and specifying how the standards upon which the IHE Technical Framework is based should be applied.

1.6.1 Actor and Transaction Diagrams and Tables

Each integration profile is a representation of a real-world capability that is supported by a set of actors that interact through transactions. Actors are information systems or components of information systems that produce, manage, or act on categories of information required by operational activities in the enterprise. Transactions are interactions between actors that transfer the required information through standards-based messages.

The tables of actors and transactions given in sections 3 - 14 indicate which transactions each actor in a given profile must support.

The convention used in these diagrams is that the arrow indicating the direction for the transaction points from the initiator of the transaction to the destination.

In some cases, a profile is dependent on a pre-requisite profile in order to function properly and be useful. For example, Presentation of Grouped Procedures depends on both Scheduled Workflow and Consistent Presentation of Images being implemented as pre-requisites. These dependencies can be found by locating the desired profile in Table 2-1 and seeing which profiles are listed as required pre-requisites.

An actor must implement all required transactions in the pre-requisite profiles in addition to those in the desired profile. In some cases, the pre-requisite is that the actor selects any one of a given set of profiles to satisfy the pre-requisite. For example, Post-processing depends on any one of the content profiles being supported.

1.6.2 Process Flow Diagrams

The descriptions of integration profiles that follow include Process Flow Diagrams that illustrate how the profile functions as a sequence of transactions between relevant actors.

These diagrams are intended to provide a “big picture” so the transactions can be seen in the context of the overall workflow. Certain transactions and activities not defined in detail by IHE are shown in these diagrams in *italics* to provide additional context on where the relevant IHE transactions fit into the broader scheme of healthcare information systems.

These diagrams are not intended to present the only possible scenario. Often other actor groupings are possible, and complementary transactions from other profiles may be interspersed. In some cases the sequence of transactions may be flexible. Where this is

the case there will generally be a note pointing out the possibility of variations.
The convention used in these diagrams is that the arrow on the line for the transaction points from the initiator of the transaction to the destination.

1.6.3 Normative versus informative contents of the Technical Framework

Most parts of the Technical Framework describe required or optional characteristics of Integration Profiles, Actors and Transactions: these are normative. For a better understanding of the text, there also exist illustrating parts in the Technical Framework that are informative and non-normative.
According to IETF RFC 2119, certain words indicate whether a specific content of the Technical Framework is normative: either required (e.g. “must”, “required”, “shall”) or optional (e.g. “may”, “recommended”). Informative content does not contain these key words.

1.6.4 Technical Framework Referencing

When references are made to a section within the same Technical Framework volume, a section number is used by itself. When references are made to other volumes or to a Technical Framework in another domain, the following format is used:
<domain designator> TF-<volume number>: <section number>, where
<domain designator> is a short designator for the IHE domain (ITI = IT Infrastructure, RAD = Radiology)
<volume number> is the applicable volume within the given Technical Framework (e.g., 1, 2, 3), and
<section number> is the applicable section number.
For example: ITI TF-1: 3.1 refers to section 3.1 in volume 1 of the IHE IT Infrastructure Technical Framework, RAD TF-3: 4.33 refers to section 4.33 in volume 3 of the IHE Radiology Technical Framework.
When references are made to specific transactions (transaction numbers) the following format is used:
<domain designator>-<transaction number>
For example RAD-4 refers to transaction number 4 (Procedure Scheduled) in the Radiology Technical Framework.

1.9 Copyright Permission

1.10 IHE Radiology Technical Framework Development and Maintenance Process

The Technical Framework is being continuously extended and maintained by the IHE Technical Committee. The Development and Maintenance Process of the Framework follows a number of principles to ensure stability of the specification both vendors and users may rely upon in specifying, developing and acquiring IHE compatible products. The process is intended to address the need for extensions, clarifications and corrections while maintaining backward compatibility of framework definitions as to support implementations claiming conformance to any previously defined Integration Profile and its Actors.
To maintain stability of the IHE Technical Framework, modifications occur in a regular annual cycle (Figure 1.10-1) according to one of two controlled paths:

1. New Development – Extending the Existing Technical Framework

Each year, new functionality to be developed is identified by the IHE Planning Committee. The Technical Committee performs the necessary analysis and design work and generates new text for the Technical Framework.
Generally, new functionality is published in the form of a Supplement. The scope of a Supplement is to make one of the following additions to the Technical Framework:

- A new Integration Profile, usually including the introduction of new Actors and Transactions.
- New Actors in an existing Integration Profile: These may be either Actors previously defined elsewhere in the Technical Framework, or new ones not yet defined. Transactions identifying the new actors responsibilities in this profile are identified or defined and may be designated as required or optional. To avoid causing compatibility problems for systems that have already

implemented that profile, no new required Transactions are added for existing Actors in the profile.

- New Options in an existing Integration Profile: These usually add optional Transactions for existing actors in the profiles, or add optional features within existing Transactions.
- Major conceptual changes: They do not change the behavior of existing Integration Profiles but may imply changes or additions to Actors or Transactions in the future. The publication process consists of certain phases and is clearly indicated on each document.

First, the text is published for **Public Comment** (with a "PC" designation). During the Public Comment period (typically 30 days), the text and a comment submission facility are available on the IHE Website. Following this period, the Technical Committee will review the comments.

Updated text of Supplements is then published for **Trial Implementation** (with a "TI" designation), based on the modifications resulting from the comments received.

After trial implementations have been judged to have sufficiently exercised the new functionality (e.g. due to experience from the Connect-a-thon), and the text is considered sufficiently stable, the new text will be published as **Final Text** (with a "FT" designation).

Final Text Supplements will be merged at the end of the annual development cycle with the current version of the Technical Framework resulting in a new version of the Technical Framework with an increased version number.

2. Maintenance of existing Technical Framework content

Despite the best efforts of the Technical Committee, a published current version of the Technical Framework or Trial Implementation documents may contain text that is incorrect, incomplete or unclear. Such issues are handled as Change Proposals and cover:

- Corrections: technical issues causing non-interoperability of implementations are fixed without introducing changes in functionality of a stable Integration Profile.
- Clarifications: text that can be misunderstood or is ambiguous is made easier to understand or disambiguated, without introducing any technical changes.

The publication process is the same for both Corrections and Clarifications, and

addresses both changes to Trial Implementations and changes to a current version of the Technical Framework.

A **Submitted Change Proposal** results from issues raised by users, vendors or Technical Committee members, e.g. from experiences with Trial Implementation or Final Text Integration Profiles or at a Connectathon. The resulting Change Proposal document should explicitly state:

- the parts of the Technical Framework requested to be changed,
- a problem description,
- a rationale why the change is considered necessary,
- and a solution or approach to the problem.

The Technical Committee regularly considers Change Proposals which are then either accepted or rejected.

A **Rejected Change Proposal** is published with a rationale from the Technical Committee explaining why the change is not appropriate. An **Accepted Change Proposal** is assigned to a member of the Technical Committee as a work item for further investigation with the goal to produce adequate clarifications or corrections. The resulting text will again be reviewed by the Technical Committee before being approved.

Once approved, a **Final Text Change Proposal** is published by the Technical Committee, and then is to be considered as effective. It will be merged into the next version of the Technical Framework at the end of the annual development cycle. Submitting a Change Proposal to a Final Text Change Proposal or a Final Text Supplement is not possible.

The current version of the Technical Framework is considered the primary reference document. Final Text Supplements and Final Text Change Proposals from the current annual cycle complement this document. Past Final Text documents are retained to provide convenient summaries of differences to prior versions of the Technical Framework or Trial Implementation versions of Supplements.

During the annual development and maintenance cycle, it is recommended to use Technical Framework documents for implementations as follows:

- Product Implementations Products implemented based on Trial Implementation text are expected to review the subsequent Final Text and update their products as necessary. Further, it is expected that vendors will monitor Final Text Change

Proposals and make any corrections relevant to their product in a timely fashion.

• Connectathon Implementations Testing at the Connectathon will be based on the current version of the Technical Framework for the appropriate IHE Domain, plus any relevant Supplements for Trial Implementation and Final Text Change Proposals.

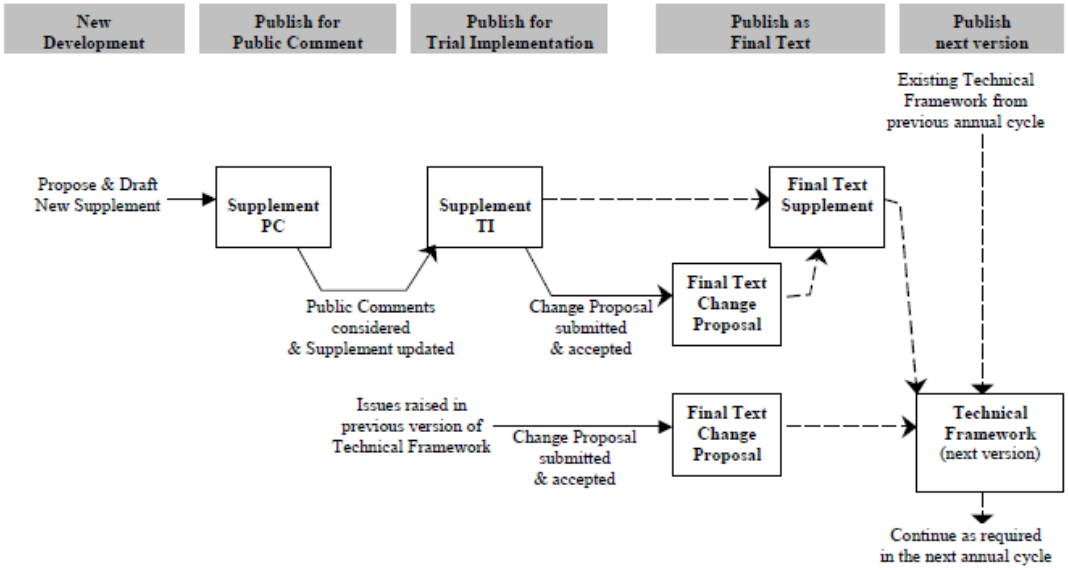


Figure 1.10-1. The figure shows the process of developing and maintaining the Technical Framework during an annual cycle. Dashed arrows indicate the assembly (merging) of text.

2 Integration Profiles

IHE Integration Profiles, depicted in Figure 2-1, offer a common language that healthcare professionals and vendors may use in communicating requirements for the integration of products. Integration Profiles describe real-world scenarios or specific sets of capabilities of integrated systems. An Integration Profile applies to a specified set of actors and for each actor specifies the transactions necessary to support those capabilities.

Integration Profiles provide a convenient way for both users and vendors to reference a subset of the functionality detailed in the IHE Technical Framework. They enable users and vendors to be more specific than simply requesting or promising overall IHE support, without laborious restatement of the details regarding IHE actors and transactions defined by the IHE Technical Framework.

The Profiles can be considered in three classes: Content Profiles which address the management of a particular type of content object; Workflow Profiles which address the management of the workflow process by which content is created; and

Infrastructure Profiles which address departmental issues. Figure 2-1 shows the current set of IHE Integration Profiles organized around these classes.

The Content Profiles describe the creation, storage, management, retrieval and general use of a particular type of content object. Current Content Profiles include: Consistent Presentation of Images, Key Image Notes, NM Image, Mammography Image, Evidence Documents, and Simple Image and Numeric Reports. Additionally, the handling of image content is described inside the Scheduled Workflow Profile. Content Profiles are “workflow neutral”. The profile addresses how the object is created, stored, queried and retrieved, but does not address the workflow management process.

The Workflow Profiles address managing workflow process, which typically involves providing worklists, and reporting/monitoring the progress and completion of workitems. Within this context, one or more content objects are generally created according to their content profile. Current Workflow Profiles include: Scheduled Workflow (for acquisition), Post-Processing Workflow, Reporting Workflow, Cross-enterprise Document Sharing for Imaging and Import Reconciliation Workflow. Presentation of Grouped Procedures is an extension of Scheduled Workflow. Charge Posting is an extension of all the Workflow Profiles.

The Infrastructure Profiles address general departmental issues like Radiology Audit Trail Option and Access to Radiology Information.

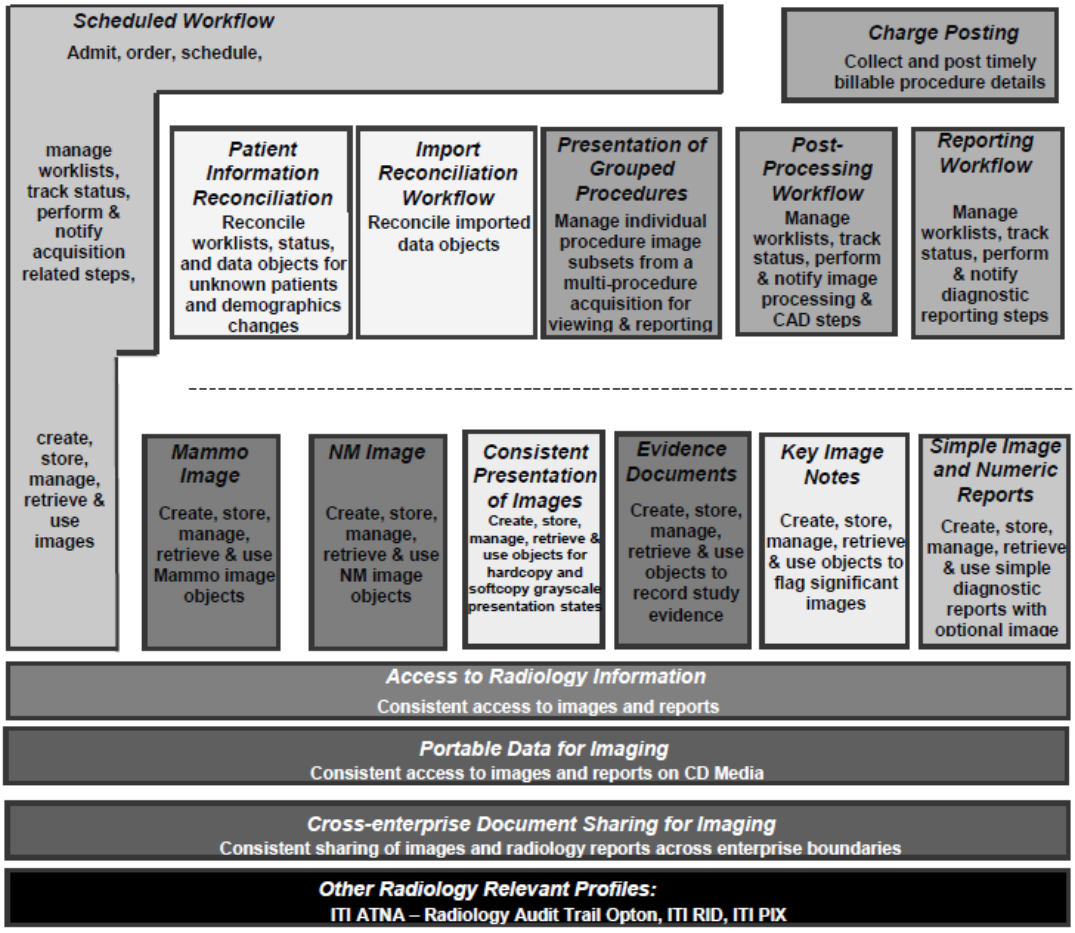


Figure 2-1. IHE Integration Profiles

Dependencies among Integration Profiles

In general, IHE Integration Profiles do not operate independently. Objects that serve as useful input to one profile may have been produced as a result of implementing another profile.

Figure 2-1 (above) provides a graphical view of the dependencies between Integration Profiles. The arrows in the diagram point from the dependent profile to the profile(s) on which it relies. In addition, dashed arrows indicate that the dependent profile requires **one or more** of the profiles it has dashed arrows pointing to.

Table 2-1 defines the required dependencies between the Integration Profiles in a tabular form.

In some cases a profile is strictly dependent on one or more profiles in order to function. For example, Presentation of Grouped Procedures depends directly on the features of Scheduled Workflow and Consistent Presentation of Images in order to function.

In other cases a profile is dependent on one of a class of profiles in order to be useful.

For example, Charge Posting depends on at least one of the workflow profiles (Scheduled Workflow, Post-Processing Workflow and/or Reporting Workflow) being present in order for it to have something useful to post. Similarly, each workflow profile is of little value unless at least one relevant content profile is also implemented. Of course the more content profiles are supported, the more forms of input and output can be managed by the workflow.

There are of course other useful synergies that occur when different combinations of profiles are implemented, but those are not described in the table below.

Table 2-1. Integration Profiles Dependencies

Integration Profile	Depends on	Dependency Type	Comments
Consistent Presentation of Images	*None*	*None*	-
Key Image Notes	*None*	*None*	-
NM Image	*None*	*None*	
Mammography Image	*None*	*None*	
Evidence Documents	*None*	*None*	-
Simple Image and Numeric Report	*None*	*None*	-
Access to Radiology Information	One or more of : {Scheduled Workflow Consistent Presentation of Images, Evidence Documents, Key Image Notes, Simple Image and Numeric Reports} Patient Information Reconciliation	Required for Content output Conditionally Required for the Multi Source option	Supporting the image related transactions of Scheduled Workflow counts as a Content profile
Scheduled Workflow	*None*	*None*	-
Presentation of Grouped Procedures	Scheduled Workflow	Required for workflow	-
	Consistent Presentation of Images	Required for Content output	-
Post-Processing Workflow	Scheduled Workflow	Required for workflow management	-
	One or more of : {Scheduled Workflow, Evidence Documents, NM Image}	Required for Content input	Supporting the image related transactions of Scheduled Workflow counts as a Content profile

Integration Profile	Depends on	Dependency Type	Comments
	One or more of : {Scheduled Workflow Consistent Presentation of Images, Evidence Documents, Key Image Notes}	Required if any output is produced	Supporting the image related transactions of Scheduled Workflow counts as a Content profile
Reporting Workflow	Scheduled Workflow	Required for workflow management	-
	One or more of : {Scheduled Workflow, Evidence Documents, NM Image}	Required for Content input	Supporting the image related transactions of Scheduled Workflow counts as a Content profile.
	Simple Image and Numeric Reports	Required for Content input/output	-
Charge Posting	One or More of : {Scheduled Workflow, Post-Processing Workflow, Reporting Workflow, Import Reconciliation Workflow}	Required for charge trigger input	-
Patient Information Reconciliation	Scheduled Workflow	Required for workflow/content to manage	Patient Information Reconciliation is an extension to this profile requiring that the workitems and/or content be updated.
Portable Data for Imaging	*None*	*None*	-
XDS for Imaging	XDS (ITI)	Document Consumer, Document Registry, and Document Repository actors from ITI XDS are required for XDS-I.	Document content types and metadata are specialized.
Import Reconciliation Workflow	Scheduled Workflow	Required for Workflow (including Scheduled Import Option)	Support the workflow related transactions of Scheduled Workflow.
	Patient Demographics Query [ITI]	Required for Unscheduled Import Option	Patient Demographic information is obtained using Patient Demographic Query.

2.1 Integration Profiles Overview

In this document, each IHE Integration Profile is defined by:

• The IHE Actors involved
• The specific set of IHE Transactions required for each IHE Actor.

These requirements are presented in the form of a table of transactions required for each actor supporting the Integration Profile. Actors supporting multiple Integration Profiles are required to support all the required transactions of each Integration Profile supported. When an Integration Profile depends upon another Integration Profile, all transactions required for the dependent Integration Profile have been included in the table.

As mentioned earlier, there is a class of Profiles that deal primarily with data content. Most types of content belong to the family of Evidence Objects. Currently this means Images, Presentation States, Key Image Notes and Evidence Documents. Evidence Objects are generated as a result of performing procedure steps on systems in the radiology department. These objects are used by the Radiologist in the process of creating a Radiological Diagnostic Report and are managed inside the Radiology Department. Evidence Documents represent the uninterpreted information that is primarily managed and used inside Radiology, although distribution outside Radiology is not precluded. In contrast, the diagnostic reports described in the Simple Image and Numeric Reports Profile represent the interpreted information which is the primary output of the Radiology department and are available for wide distribution.
Note that IHE Integration Profiles are not statements of conformance to standards, and IHE is not a certifying body. Users should continue to request that vendors provide statements of their conformance to relevant standards, such as DICOM and HL7. Standards conformance is a prerequisite for vendors adopting IHE Integration Profiles.
Also note that there are critical needs for any successful integration project that IHE cannot address. Successfully integrating systems still requires a project plan that minimizes disruptions and describes fail-safe strategies, specific and mutually understood performance expectations, well-defined user interface requirements, clearly identified systems limitations, detailed cost objectives, plans for maintenance and support, etc.

2.1.13 Portable Data for Imaging (PDI)

The Portable Data for Imaging Integration Profile specifies actors and transactions that allow users to distribute imaging related information on interchange media. The intent of this profile is to provide reliable interchange of evidence objects and diagnostic reports for import, display or print by a receiving actor. A single physical transport means is specified that supports the multiple usage scenarios described in this profile. The CD format was chosen for supporting the described use cases.

2.2 Options to other Domains' Profiles

2.3 Actor Descriptions

Actors are information systems or components of information systems that produce, manage, or act on information associated with operational activities in the enterprise. The following are the actors defined by IHE and referenced throughout the rest of this

document.

It is acknowledged that some of the terms used as modifiers for the actor names are not used consistently (e.g., Evidence Creator, Image Display). At this point, the benefit in doing extensive renaming to gain consistency is outweighed by the risk of introducing significant confusion that would result from renaming many of the existing actors. Therefore the actor names will remain as defined below.

2.3 Actor Descriptions

Actors are information systems or components of information systems that produce, manage, or act on information associated with operational activities in the enterprise. The following are the actors defined by IHE and referenced throughout the rest of this document.

It is acknowledged that some of the terms used as modifiers for the actor names are not used consistently (e.g., Evidence Creator, Image Display). At this point, the benefit in doing extensive renaming to gain consistency is outweighed by the risk of introducing significant confusion that would result from renaming many of the existing actors. Therefore the actor names will remain as defined below.

Acquisition Modality – A system that acquires and creates medical images while a patient is present, e.g. a Computed Tomography scanner or Nuclear Medicine camera. A modality may also create other evidence objects such as Grayscale Softcopy Presentation States for the consistent viewing of images or Evidence Documents containing measurements.

ADT Patient Registration – A system responsible for adding and/or updating patient demographic and encounter information. In particular, it registers a new patient with the Order Placer and Department System.

Charge Processor – Receives the posted charges and serves as a component of the financial system. Further definition of this actor is beyond current IHE scope.

Department System Scheduler/Order Filler – A department-based information system (for instance, Radiology or Laboratory) that provides functions related to the management of orders received from external systems or through the department system’s user interface. Upon a defined workflow action, makes procedures available for charge posting. The action/event that actually causes charges to post is defined by the actor.

Display – Primary description for this actor can be found in ITI TF-1: Appendix A. The required capabilities for its use within the Radiology Technical Framework add the ability to view "web-viewable" diagnostic and therapeutic imaging information

on interchange media.

Document Consumer – The Document Consumer actor queries a Document Registry actor for documents meeting certain criteria, and retrieves selected documents from one or more Document Repository actors.

Document Registry – The Document Registry actor maintains meta-data about each registered document in a document entry. This includes a link to the Document Repository where the actual document is stored. The Document Registry responds to queries from Document Consumer actors about documents meeting specific criteria. It also enforces some healthcare specific technical policies at the time of document registration.

Document Repository – The Document Repository actor persistently stores documents. It assigns and maintains a unique identifier for each document, to allow Document Consumers to retrieve them.

Enterprise Report Repository – A system that receives Structured Report Export Transactions from the Report Manager and stores them.

Evidence Creator – A system that creates additional evidence objects such as images, presentation states, Key Image Notes, and/or Evidence Documents and transmits them to an Image Archive. It also makes requests for storage commitment to the Image Manager for the data previously transmitted. It may also retrieve worklist entries for post-processing steps from the Post-Processing Manager and provide notification of completion of the step, allowing the enterprise to track the status of post-processing work.

External Report Repository Access – A system that performs retrieval of clinical reports containing information generated outside the imaging department and presented as DICOM Structured Reporting Objects.

Image Archive – A system that provides long term storage of evidence objects such as images, presentation states, Key Image Notes and Evidence Documents.

Image Display – A part of a system that can access imaging evidence objects (images, Presentation States, Key Image Notes, Evidence Documents) through network query/retrieve or reading interchange media and allow the user to view these objects.

Image Manager – A system that provides functions related to safe storage and management of evidence objects. It supplies availability information for those objects to the Department System Scheduler.

Imaging Document Consumer – The Imaging Document Consumer actor parses an imaging manifest document that is retrieved by the Document Consumer actor from the Document Repository actor, and retrieves DICOM SOP Instances referenced

within that manifest from the Imaging Document Source actor.

Imaging Document Source – The Imaging Document Source actor is the producer and publisher of imaging documents. It is responsible for providing imaging documents and meta-data to the Document Repository actor, which subsequently registers the imaging documents with the Document Registry actor. It also supports the retrieval services for DICOM SOP Instances referenced in a published imaging manifest document.

Importer – A system that imports evidence objects such as images, presentation states, Key Image Notes or Evidence Documents from hardcopy or digital media.

Master Patient Index (MPI) – A system that maintains unique enterprise-wide identifiers for patients. Note that this is not supported in the current scope of the IHE Technical Framework

Order Placer – A hospital or enterprise-wide system that generates orders for various departments and distributes those orders to the correct department.

Patient Demographics Supplier – A repository of patient information that can be searched on demographic related fields. This actor is defined in the ITI Technical Framework.

Performed Procedure Step Manager – A system that re-distributes the Modality Performed Procedure Step information from the Acquisition Modality or Evidence Creator to the Department System Scheduler/Order Filler, Image Manager and Report Manager.

Portable Media Creator – This actor assembles the content of the media and writes it to the physical medium.

Portable Media Importer – This actor reads the DICOM information contained on the media, and allows the user to select DICOM instances, reconcile key patient and study attributes, and store these instances. The actor grouped with the Media Importer can then process the instances.

Post-Processing Manager – A system that provides functions related to post-processing worklist management. This involves the ability to schedule post-processing worklist items (scheduled procedure steps), provide worklist items to post-processing worklist clients, and update the status of scheduled and performed procedure steps as received from post-processing worklist clients.

Print Composer – A system that generates DICOM print requests to the Print Server. Print requests include presentation state information in the form of Presentation Look-Up Tables (Presentation LUTs). It may also read the DICOM information contained on interchange media.

Print Server – A system that accepts and processes DICOM print requests as a DICOM Print SCP and performs image rendering on hardcopy media. The system must support pixel rendering according to the DICOM Grayscale Standard Display Function.

Report Creator – A system that generates and transmits draft (and optionally, final) diagnostic reports, presenting them as DICOM Structured Reporting Objects. It may also retrieve worklist entries for reporting steps from the Report Manager and provide notification of completion of the step, allowing the enterprise to track the status of an awaited report.

Report Manager – A system that provides management and short-term storage of DICOM Structured Report objects during the reporting process then distributes text or structured reports to report repositories. It also manages the worklists and status of reporting.

Report Reader – A part of a system that can access reports through network query/retrieve or reading interchange media and allow the user to view reports presented as DICOM Structured Reporting Objects.

Report Repository – A system that provides long-term storage of diagnostic reports and their retrieval as DICOM Structured Reporting Objects.

The following table shows which actors are used in which Integration Profiles.

Table 2.3-1. Integration Profile Actors

Integration Profile / Actor	SWF	PIR	PWF	RWF	CHG	CPI	PGP	KIN	ED	NM	SINR	PDI	ARI	XDS-I	MAMMO	IRWF
Acq. Modality	X	X			X	X	X	X	X	X					X	
ADT Patient Reg.	X	X			X											
Charge Processor					X											
Display (ITI)												X				
Document Consumer														X		
Document Registry														X		
Document Repository														X		
DSS/OF	X	X	X	X	X		X									X
Enterprise Rep. Repository											X					
Evidence Creator	X		X		X	X		X	X	X					X	
Ext. Rep. Access											X		X			
Image Archive	X	X	X	X		X	X	X	X	X			X		X	X
Image Display	X		X			X		X	X	X		X	X		X	

Integration Profile / Actor	SWF	PIR	PWF	RWF	CHG	CPI	PGP	KIN	ED	NM	SINR	PDI	ARI	XDS-I	MAMMO	IRWF
Image Manager	X	X	X	X		X	X	X	X	X			X		X	X
Imaging Document Consumer														X		
Imaging Document Source														X		
Importer					X											X
Order Placer	X	X														
Patient Demographics Supplier																X
Portable Media Creator												X				
Portable Media Importer												X				
Post-Processing Manager			X		X											
PPS Manager	X	X		X	X		X									X
Print Composer						X						X			X	
Print Server						X									X	
Report Creator				X					X		X					
Report Manager		X		X	X						X					
Report Reader				X							X	X	X			

Integration Profile / Actor	SWF	PIR	PWF	RWF	CHG	CPI	PGP	KIN	ED	NM	SINR	PDI	ARI	XDS-I	MAMMO	IRWF
Report Repository		X									X		X			

2.4 Transaction Descriptions

Transactions are interactions between actors that transfer the required information through standards-based messages. The following are the transactions defined by IHE and referenced throughout the rest of this document.

1. **Patient Registration –** The ADT system registers and/or admits a patient and forwards the information to other information systems.
2. **Placer Order Management** – The Order Placer informs the Order Filler of the initiation or cancellation of an order. The Placer/Filler Order Management transaction will sometimes be referred to as "-New" when a new order is being initiated, or as "-Cancel" when an existing order is canceled.
3. **Filler Order Management** – The Order Filler informs the Order Placer of the initiation, cancellation, or change in the status of an order. The Placer/Filler Order Management transaction will sometimes be referred to as "-New" when a new order is being initiated, or as "-Cancel" when an existing order is canceled.
4. **Procedure Scheduled –** Schedule information is sent from the Department System Scheduler/Order Filler to the Image Manager and to the Report

Manager.

5. **Query Modality Worklist –** In response to a query (with optional filtering) a list of Scheduled Procedure Steps with selected demographic and order information is returned.
6. **Modality Procedure Step In Progress –** An Acquisition Modality notifies the Performed Procedure Step Manager of the start of a new Procedure Step and the PPS Manager informs the Department System, Image Manager and the Report Manager.
7. **Modality Procedure Step Completed –** An Acquisition Modality notifies the Performed Procedure Step Manager of the completion of a Procedure Step and the PPS Manager informs the Department System, Image Manager and the Report Manager.
8. **Modality Images Stored –** An Acquisition Modality sends acquired or generated images to the Image Archive.
9. **Modality Presentation State Stored –** An Acquisition Modality requests that the Image Archive store a Grayscale Softcopy Presentation State (GSPS) for the acquired or generated images.
10. **Storage Commitment –** A requestor (Acquisition Modality or Evidence Creator) requests that the Image Manager confirm ownership for the specified DICOM objects (images, GSPS objects, Key Image Notes, Evidence Documents or any combination thereof) that the requestor stored in the Image Archive, thus allowing the sender to delete those objects now owned by the Image Manager.
11. **Images Availability Query –** The Department System Scheduler/Order Filler and Report Manager asks the Image Manager if a particular image or image series is available.
12. **Patient Update –** The ADT Patient Registration System informs the Order Placer and the Department System Scheduler/Order Filler of new information for a particular patient. The Department System Scheduler may then further inform the Image Manager and Report Manager.
13. **Procedure Update –** The Department System Scheduler/Order Filler sends the Image Manager and Report Manager updated order or procedure information.
14. **Query Images –** An Image Display queries the Image Archive for a list of entries representing images by patient, study, series, or instance.
15. **Query Presentation States –** An Image Display queries the Image Archive for a list of entries representing image Grayscale Softcopy Presentation States

(GSPS) by patient, study, series, or instance.

16. **Retrieve Images –** An Image Display or an Imaging Document Consumer requests and retrieves a particular image or set of images from the Image Archive or an Imaging Document Source, respectively.
17. **Retrieve Presentation States –** An Image Display or an Imaging Document Consumer requests and retrieves the Grayscale Softcopy Presentation State (GSPS) information for a particular image or image set.
18. **Creator Images Stored –** An Evidence Creator sends new images to the Image Archive.
19. **Creator Presentation State Stored –** An Evidence Creator requests that the Image Archive store the created Grayscale Softcopy Presentation State objects.
20. **Creator Procedure Step In Progress –** An Evidence Creator notifies the Performed Procedure Step Manager of the start of a new Procedure Step and the PPS Manager informs the Department System and Image Manager.
21. **Creator Procedure Step Completed –** An Evidence Creator notifies the Performed Procedure Step Manager of the completion of a Procedure Step and the PPS Manager informs the Department System and Image Manager.
22. **Intentionally unassigned**
23. **Print Request with Presentation LUT –** A Print Composer sends a print request to the Print Server specifying Presentation LUT information.
24. **Report Submission –** A Report Creator sends a draft or final diagnostic report to the Report Manager.
25. **Report Issuing –** A Report Manager sends a draft or final diagnostic report to the Report Repository.
26. **Query Reports –** A Report Reader provides a set of criteria to select the list of entries representing diagnostic reports by patient, study, series, or instance known by the Report Repository or External Report Repository Access.
27. **Retrieve Reports –** A Report Reader or an Imaging Document Consumer requests and retrieves a diagnostic report from the Report Repository, External Report Repository Access or an Imaging Document Source.
28. **Structured Report Export** – A Report Manager composes an HL7 Result transaction by mapping from DICOM SR and transmits it to the Enterprise Report Repository for storage.
29. **Key Image Note Stored** – An Acquisition Modality or an Evidence Creator sends a Key Image Note to the Image Archive

30. **Query Key Image Notes** – An Image Display queries the Image Archive for a list of entries representing Key Image Notes by patient, study, series, or instance.
31. **Retrieve Key Image Note** – An Image Display or an Imaging Document Consumer requests and retrieves a Key Image Note from the Image Archive or an Imaging Document Source, respectively.
32. **Authenticate Node [DEPRECATED]** – This transaction is identical to, and has been superseded by the Authenticate Node as part of the ITI Audit Trail and Node Authentication Profile (ITI TF-II 3.19).
33. **Maintain Time [DEPRECATED]** – This transaction identical to, and has been superseded by the Maintain Time as part of the ITI Consistent Time Profile (ITI TF-II 3.1).
34. **Record Audit Event [DEPRECATED]** – This transaction has been superseded by the Record Audit Event as part of the ITI Audit Trail and Node Authentication Profile (ITI TF-II 3.20).
35. **Charge Posted** - The Department System Scheduler/Order Filler sends descriptions of potential procedure and material charges.
36. **Account Management** – The ADT Patient Registration Actor informs the Charge Processor about creation, modification and ending of the patient's account.
37. **Query Post-Processing Worklist** – Based on a query from a worklist client (Evidence Creator), a worklist is generated by the worklist manager (Post-Processing Manager) containing either Post-Processing or Computer Aided Detection (CAD) workitems that satisfy the query. Workitems are returned in the form of a list of General Purpose Scheduled Procedure Steps.
38. **Workitem Claimed** – A worklist client (Evidence Creator, Report Creator) notifies the worklist provider (Post-Processing Manager, Report Manager) that it has claimed the workitem.
39. **Workitem PPS In Progress** – A worklist client (Evidence Creator, Report Creator) notifies the worklist provider (Post-Processing Manager, Report Manager) that it has started work (i.e. created a General Purpose Performed Procedure Step).
40. **Workitem PPS Completed** – A worklist client (Evidence Creator, Report Creator) notifies the worklist provider (Post-Processing Manager, Report Manager) of the completion of a General Purpose Performed Procedure Step.
41. **Workitem Completed** – A worklist client (Evidence Creator, Report Creator)

notifies the worklist provider (Post-Processing Manager, Report Manager) that it has finished the workitem (i.e. completed a General Purpose Scheduled Procedure Step).

42. **Performed Work Status Update** – The worklist provider informs other interested actors of the on-going status and completion of performed work.
43. **Evidence Document Stored** – A source actor of Evidence Documents (Acquisition Modality or Evidence Creator) sends recorded, measured or derived diagnostic evidence in the form of a DICOM Structured Report to the Image Archive.
44. **Query Evidence Documents** – A user of Evidence Documents (Image Display, Report Creator or Report Reader) queries the Image Archive for a list of entries representing Evidence Documents.
45. **Retrieve Evidence Documents** – A user of Evidence Documents (Image Display, Report Creator or Report Reader) or an Imaging Document Consumer requests and retrieves an Evidence Document from the Image Archive or an Imaging Document Source, respectively.
46. **Query Reporting Worklist** – Based on a query from a Report Creator worklist client, a worklist is generated by the Report Manager containing reporting task workitems that satisfy the query. Workitems are returned in the form of a list of General Purpose Scheduled Procedure Steps.
47. **Distribute Imaging Information on Media** – A source actor (Portable Media Creator) writes image data, other evidence objects and reports onto a piece of interchange media. The media is physically transported to another actor (Portable Media Importer, Image Display, Report Reader, Display or Print Composer) which then imports, displays or prints the evidence objects and reports. The media can also be provided to a patient or a referring physician for web-based viewing.
48. **Appointment Notification** – The Department System Scheduler/Order Filler sends the Order Placer actor the date and time of the appointment(s) related to one or more Scheduled Procedure Step(s).
49. **Instance Availability Notification** – The Image Manager/Image Archive notifies interested workflow actors (such as the Department System Scheduler/Order Filler, Post-Processing Manager and Report Manager) about the availability status of instances at specified storage locations.
50. **Intentionally, temporarily Left Blank**
51. **Intentionally, temporarily Left Blank**

52. **Intentionally, temporarily Left Blank**
53. **Intentionally, temporarily Left Blank**
54. **Provide and Register Imaging Document Set** - An Imaging Document Source actor initiates the Provide and Register Imaging Document Set transaction. For each document in the Submission Set, the Imaging Document Source actor provides both the documents as an opaque octet stream and the corresponding meta-data to the Document Repository. The Document Repository is responsible to persistently store these documents, and to register them in the Document Registry using the Register Documents transaction by forwarding the document meta-data received from the Imaging Document Source Actor. [RAD-54, derived from ITI-15].
55. **WADO Retrieve** – A WADO Retrieve transaction is issued by an Imaging Document Consumer to an Imaging Document Source to retrieve DICOM objects over HTTP/HTTPS protocol [RAD-55].
56. **Intentionally, temporarily Left Blank**
57. **Intentionally, temporarily Left Blank**
58. **Intentionally, temporarily Left Blank**
59. **Import Procedure Step In Progress** – The Performed Procedure Step Manager receives progress notification of an importation Procedure Step and in turn notifies the Order Filler, Image Manager and the Report Manager.
60. **Import Procedure Step Completed** – The Performed Procedure Step Manager receives completion notification of an importation Procedure Step and in turn notifies the Order Filler, Image Manager and the Report Manager.
61. **Imported Objects Stored** – A system importing DICOM Objects or digitized hardcopy sends imported DICOM Composite Objects to the Image Archive.

The following table shows which transactions are used in which Integration Profiles

Table 2.4-1. Integration Profile Transactions

Integration Profile Transaction	SWF	PIR	PWF	RWF	CHG	CPI	PGP	KIN	ED	NM	SINR	PDI	ARI	XDS-I	MAMMO	IRWF
Patient Registration [RAD-1]	X															
Placer Order [RAD-2]	X															
Filler Order [RAD-3]	X															
Procedure Scheduled [RAD-4]	X			X												
Query Modality Worklist [RAD-5]	X	X														X
Modality Procedure Step In Progress [RAD-6]	X	X					X									
Modality Procedure Step Completed [RAD-7]	X	X		X	X		X									
Modality Images Stored [RAD-8]	X	X				X				X					X	
Modality Presentation State Stored [RAD-9]						X	X									
Storage Commitment [RAD-10]	X	X				X		X	X	X					X	X
Images Availability Query [RAD-11]	X	X	X	X												
Patient Update [RAD-12]	X	X														
Procedure Update [RAD-13]	X	X		X												
Query Images [RAD-14]	X		X			X		X		X			X		X	

Integration Profile Transaction	SWF	PIR	PWF	RWF	CHG	CPI	PGP	KIN	ED	NM	SINR	PDI	ARI	XDS-I	MAMMO	IRWF
Query Presentation States [RAD-15]						X							X			
Retrieve Images [RAD-16]	X	X	X	X		X		X		X			X		X	
Retrieve Presentation States [RAD-17]						X							X			
Creator Images Stored [RAD-18]	X		X			X				X						
Creator Presentation State Stored [RAD-19]						X										
Creator Procedure Step In Progress [RAD-20]	X				X											
Creator Procedure Step Complete [RAD-21]	X				X											
Print Request with Presentation LUT [RAD-23]						X									X	
Report Submission [RAD-24]											X	X				
Report Issuing [RAD-25]											X	X				
Query Reports [RAD-26]		X									X	X	X			
Retrieve Reports [RAD-27]		X									X	X	X			
Structured Report Export [RAD-28]											X	X				
Key Image Note Stored [RAD-29]								X								
Query Key Image Notes [RAD-30]								X					X			
Retrieve Key Image Notes [RAD-31]								X					X			
Charge Posted [RAD-35]					X											

Integration Profile Transaction	SWF	PIR	PWF	RWF	CHG	CPI	PGP	KIN	ED	NM	SINR	PDI	ARI	XDS-I	MAMMO	IRWF
Account Management [RAD-36]					X											
Query Post-Processing Worklist [RAD-37]			X													
Workitem Claimed [RAD-38]			X	X												
Workitem PPS In-Progress [RAD-39]			X	X												
Workitem PPS Completed [RAD-40]			X	X												
Workitem Completed [RAD-41]			X	X												
Performed Work Status Update [RAD-42]	X		X	X	X											
Evidence Documents Stored [RAD-43]									X						X	
Query Evidence Documents [RAD-44]									X				X		X	
Retrieve Evidence Documents [RAD-45]									X				X		X	
Query Reporting Worklist [RAD-46]		X		X												
Distribute Imaging Information on Media [RAD-47]												X				
Appointment Notification [RAD-48]	X															
Instance Availability Notification [RAD-49]	X															
Intentionally left blank [RAD-50]																

Integration Profile Transaction	SWF	PIR	PWF	RWF	CHG	CPI	PGP	KIN	ED	NM	SINR	PDI	ARI	XDS-I	MAMMO	IRWF
Intentionally left blank [RAD-51]																
Intentionally left blank [RAD-52]																
Intentionally left blank [RAD-53]																
Provide and Register Imaging Document Set [RAD-54]														X		
WADO Retrieve [RAD-55]														X		
Intentionally left blank [RAD-56]																
Intentionally left blank [RAD-57]																
Intentionally left blank [RAD-58]																
Import Procedure Step In Progress [RAD-59]					X											X
Import Procedure Step Completed [RAD-60]					X											X
Import Objects Stored [RAD-61]																X

2.5 Product Implementations

Developers have a number of options in implementing IHE actors and transactions in product implementations. The decisions cover four levels of optionality:

- For a system, select which actors it will incorporate. (Multiple actors per system is acceptable).
- For each actor, select which Integration Profiles it will participate in.
- For each actor-profile, select which optional transactions will be implemented. All required transactions must be implemented for the profile to be supported. (Refer to the Integration Profile Tables in sections 3-14)

• Finally, for each transaction, select which optional features will be supported. (Refer to the transaction descriptions in TF Volume II and Volume III)

Implementers should provide a statement describing which IHE Actors, IHE Integration Profiles, optional transactions and optional features are incorporated in a given product. The recommended form for such a statement is defined in Appendix D. In general, a product implementation may incorporate any single actor or combination of actors. However, in the cases specified below, the implementation of one actor requires the implementation of one or more additional actors:

• The Image Archive shall be grouped with the Image Manager, and the Image Manager shall be grouped with the Image Archive.
• The Image Manager participating in Scheduled Workflow or Reporting Workflow Integration Profiles shall be grouped with a Performed Procedure Step Manager. The grouped Performed Procedure Step Manager shall be capable of being disabled via configuration.
• The Department System Scheduler/Order Filler participating in Scheduled Workflow or Reporting Workflow shall be grouped with a Performed Procedure Step Manager. The grouped Performed Procedure Step Manager shall be capable of being disabled via configuration.
• The Print Composer shall be grouped with an Image Manager, an Acquisition Modality, an Image Display or an Evidence Creator.
• The Evidence Creator participating in Post-Processing Workflow shall be grouped with an Image Display.
• Any Actor participating in Basic Security Profile shall be grouped with the Secure Node Actor
• The Post-Processing Manager shall be grouped with either an Image Manager or a Department System Scheduler.
• The Portable Media Importer shall be grouped with at least one of the following actors in order to perform import of the supported evidence objects and/or Diagnostic Reports:

    • Evidence Creator (Evidence Documents)
    • Acquisition Modality (Images, Key Image Notes, Evidence Documents)
    • Image Manager/Image Archive (Images, Presentation States, Key Image Notes, Evidence Documents)

    - Report Creator (Diagnostic Reports)
    - Report Manager (Diagnostic Reports)
    - Report Repository (Diagnostic Reports)
    - Importer
- The Imaging Document Consumer shall be grouped with an ITI XDS Document Consumer, thereby supporting the Document Consumer's transactions for querying an XDS Registry and Repository as defined in ITI XDS.
- The Importer Actor is generic in terms of not defining a specific transport mechanism for the Evidence Objects it imports. It may be necessary for the Importer to be grouped with additional Actors to support specific transport mechanisms. For example, to support import from PDI Media, the Importer Actor must be grouped with the Portable Media Importer Actor.

When multiple actors are grouped in a single product implementation, all transactions originating or terminating with each of the supported actors shall be supported (i.e., the IHE transactions shall be offered on an external product interface). The exceptions to this rule are any transactions defined between actors in the required groupings defined above.

For example, the Procedure Step In Progress/Completed transaction does not need to be supported between the Performed Procedure Step Manager and the Image Manager when these are grouped together in a single system. On the other hand, the Report Submission Transaction must be supported even by an implementation that groups the Report Creator and the Report Manager.

When two or more actors are grouped together, internal communication between actors is assumed to be sufficient to allow the necessary information flow to support their functionality; for example, the Image Manager provides necessary information updates to the Image Archive to support its Query/Retrieve functionality. The exact mechanisms of such internal communication are outside the scope of the IHE Technical Framework.

The following examples describe which actors typical systems might be expected to support. This is not intended to be a requirement, but rather to provide some examples to aid understanding.

- A modality system, such as an MRI scanner and console or Ultrasound system might typically include an Acquisition Modality actor and a Print Composer actor.
- An imaging workstation, such as a post-processing workstation or advanced review station might typically include an Image Display actor, an Evidence Creator actor

and a Print Composer actor.

- An HIS registration and order entry system might typically include the ADT Patient Registration actor and an Order Placer actor.
- A departmental RIS system might typically include a Department System Scheduler actor, an Order Filler actor, a Performed Procedure Step Manager actor, a Report Manager actor and a Report Reader actor.
- An Ultrasound system that generates echo report measurements would likely include an Acquisition Modality actor that supports both the Scheduled Workflow Profiles and the Evidence Documents Profile.

When an implementation has an actor supporting multiple integration profiles, the actor is required to support logical cross-behaviors/ transactions. For example, if an Evidence Creator supports the Post-Processing Workflow and Evidence Documents Profiles, then the actor must generate PPS messages when creating evidence documents. If an Image Display supports the Simple Image and Numeric Reports and Consistent Presentation of Images Profiles, then the actor must make use of any GSPS referenced by the Simple Image and Numeric Report when rendering the relevant images.

15 Portable Data for Imaging (PDI) Integration Profile

The **Portable Data for Imaging Integration Profile** specifies actors and transactions that provide for the interchange of imaging-related information on interchange media. The intent of this profile is to provide reliable interchange of image data and diagnostic reports for import, display or print by a receiving actor.

This profile addresses identification of the media content's source and the patient (where appropriate), reconciliation of data during import, and the structure of the media contents.

The central elements of the profile are:

- Reliable interchange of imaging-related information based on the DICOM standard
- A Web Content Option that provides guidelines for including web-viewable content on media

The Web Content Option addresses the case of media containing both DICOM-encoded objects and objects in XHTML or JPEG derived from these DICOM-encoded objects.

15.1 Actors/ Transactions

Figure 15.1-1 diagrams the actors directly involved in this profile and the transactions between actors.

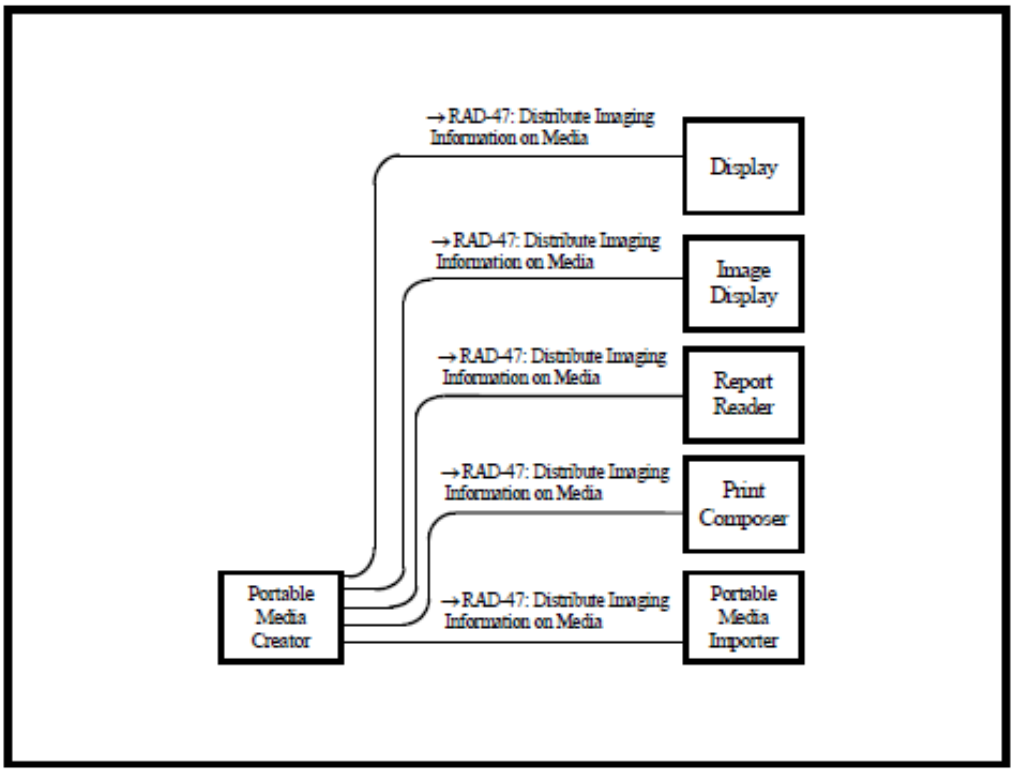


Figure 15.1-1. Portable Data for Imaging Diagram

Table 15.1-1 lists the transactions for each actor directly involved in the Portable Data for Imaging Profile. In order to claim support of this Integration Profile, an implementation shall perform the required transactions (labeled “R”). Transactions labeled “O” are optional. A complete list of options defined by this Integration Profile is listed in RAD TF-1: 15.2. Note that one of a number of actors must be grouped with Portable Media Importer as described in RAD TF-1: 2.5.

Table 15.1-1. Portable Data for Imaging Integration Profile - Actors and Transactions

Actors	Transactions	Optionality	Vol. II/III Section
Portable Media Creator	Distribute Imaging Information on Media [RAD-47]	R	4.47
Portable Media Importer	Distribute Imaging Information on Media [RAD-47]	R	4.47
Image Display	Distribute Imaging Information on Media [RAD-47]	R	4.47
Report Reader	Distribute Imaging Information on Media [RAD-47]	R	4.47
Print Composer	Distribute Imaging Information on Media [RAD-47]	R	4.47
Display (ITI TF)	Distribute Imaging Information on Media [RAD-47]	R	4.47

15.2 Portable Data for Imaging Integration Profile Options

Options that may be selected for this Integration Profile are listed in table 15.2-1 along with the Actors to which they apply. Dependencies between options when applicable are specified in notes.

Table 15.2-1: Portable Data for Imaging - Actors and Options

Actor	Options	Vol & Section
Portable Media Creator	*Web Content*	RAD TF-1: 15.4.2 RAD TF-2: 4.47.4.1.2
Portable Media Importer	*No options defined*	-
Image Display	*No options defined*	-
Report Reader	*No options defined*	-
Print Composer	*No options defined*	-
Display (ITI TF)	*No options defined*	-

15.3 Portable Data for Imaging Process Flow

This section describes the typical process flow related to the use of Interchange Media. The transaction covered is 47- Distribute Imaging Information on Media.

The following steps can be identified in this process flow:

- The source actor (Portable Media Creator) writes a group of image dataset(s) and/or the associated diagnostic report(s) onto a piece of interchange media. It is presumed that the Portable Media Creator has access to the data from a grouped actor, or another source outside the scope of IHE.
- The media is physically transported to a destination where the imaging-related

information contained on the media will be used.

- The Portable Media Importer reads DICOM objects (images, presentation states, key image notes, evidence documents and reports) on the media and imports them into the local
  information space. The Portable Media Importer reconciles the data as needed (e.g., to change the recorded Patient ID to the local Patient ID). If some classes of DICOM objects are present on the media and cannot be imported, the Portable Media Importer actor notifies the operator of the studies and series affected and makes clear that they are not supported by the importing application.
- The Image Display, Report Reader, Display or Print Composer reads the objects it supports and renders them depending on the receiver's needs. If some objects are not supported by the reading application it notifies the operator that those objects are not supported.

The potential usage scenarios of the data are described in the use cases below.

15.3.1 Use Cases

This profile is not intended to provide an archival solution.

Use Case 1 - Patient/Referring Physician Viewing: Diagnostic and therapeutic imaging data, such as images and reports, is received on media potentially serving multiple use cases. The patient or the referring physician can view the data, either with a viewer application residing on the same media or using a web browser. This data is not necessarily intended as a basis for diagnostic or therapeutic processes, and may just be informative data. For security and privacy reasons, media given to a patient would not contain data of other patients. Refer to section 15.5 for additional security considerations.

Use Case 2 - Healthcare Enterprise Interchange: One or more patients' data, such as images, reports or complete studies, is received on media to enable a diagnostic or therapeutic care process. Media data are imported at a different site, generally for the purpose of a "second read import" or "reference import".

- Second Read Import: Media data is imported to the Image Manager/Archive to be read/over read. In order to avoid data conflicts, key patient/study attributes may need to be reconciled with existing local data. Images and related presentation states can be sent to a Print Composer to be printed.
- Reference Import: Media data is imported to the Image Manager/Archive

and/or Report Repository to become part of the patient history. It may be used as “relevant prior” data for future reads. In order to avoid data conflicts, key patient/study attributes may need to be reconciled with existing local data.

Use Case 3 - Operating Room Viewing: Media data is used to enable diagnostic or therapeutic processes in environments without a reliable network connection. The volume of data can be very large and may contain image data, post-processing results and reports. In the operating room, the surgical staff receives the media and reads its contents using advanced viewing capabilities, which may include manipulating or processing images.

15.3.2 Process Flow Description

The use cases can be specified in terms of three media-related activities:

- Media Export
- Media Viewing
- Media Import

Media Export (All Use Cases):

The Portable Media Creator assembles the media content (DICOM and web-viewable content) and writes it to the physical medium.

The following sequence of activities will be performed during media creation:

- Export of DICOM data (FSC activity)
- Optionally, export of web-viewable data, which involves deriving easily accessible informative data from the DICOM data (Web Content Option).
- Optionally, inclusion of additional content (e.g.: a DICOM Viewer or viewing software components on the media to access DICOM data)

B) Media Viewing:

B1) Web (Use Case 1) (care providers, other users and patients without DICOM viewing equipment or software):

Any web-viewable media content is received and displayed by a Display actor, which exists as a generally available resource (i.e. web browser). Note that the Portable Media Creator cannot rely on the presence of web-viewable content on all media since it will be included only on media created using the Web Content Option).

B2) DICOM (Use Case 1 and 3) (users with DICOM viewing equipment or software):

The DICOM portion of the media content is displayed using specialized applications pre-existing in the reading environment or included on the media itself. The variety of DICOM objects that an Image Display and/or Report Reader actor can process is indicated by its support of the corresponding content profiles. The Print Composer actor sends images from the media to a Print Server for printing.

C) Media Import (Use Case 2):

The "Media Import" activity is accomplished by a Portable Media Importer and deals exclusively with the DICOM portion of the media content. The Portable Media Importer actor is grouped with one or more content actors (Evidence Creator, Report Creator, etc.), depending on the type of media content to be imported. The grouped actor provides storage capability for the media data accessed by the Portable Media Importer.

The Portable Media Importer actor accesses all DICOM instances referenced by the DICOMDIR file and enables the user to select a media patient dataset to be imported. The Portable Media Importer obtains local data that is known to be accurate within the importing institution/enterprise and reconciles "key attributes" of patient and study information (when required). A method for performing these steps is documented in the Import Reconciliation Workflow Profile (see Section 3.21). Refer to RAD TF-3: 4.47.4.1.3. for the list of "key attributes" and the related reconciliation actions to be performed.

Note: The Portable Media Importer may for example be grouped with an Evidence Creator to allow the storage of its diagnostic and therapeutic imaging content to an Image Manager/Image Archive, or grouped with a Report Creator to store reports an a Report Repository. This enables use of the content for subsequent "relevant prior" data for future reads. A grouping with an Acquisition Modality actor could also be used to allow subsequent "reads/over reads". In the case of a Portable Media Importer grouped with the Print Composer actor, the imported content (images and presentation states) can be sent to the Print Server to be printed.

Figure 15.3.2-1 shows an example flow of events covering the use cases described in the previous sections.

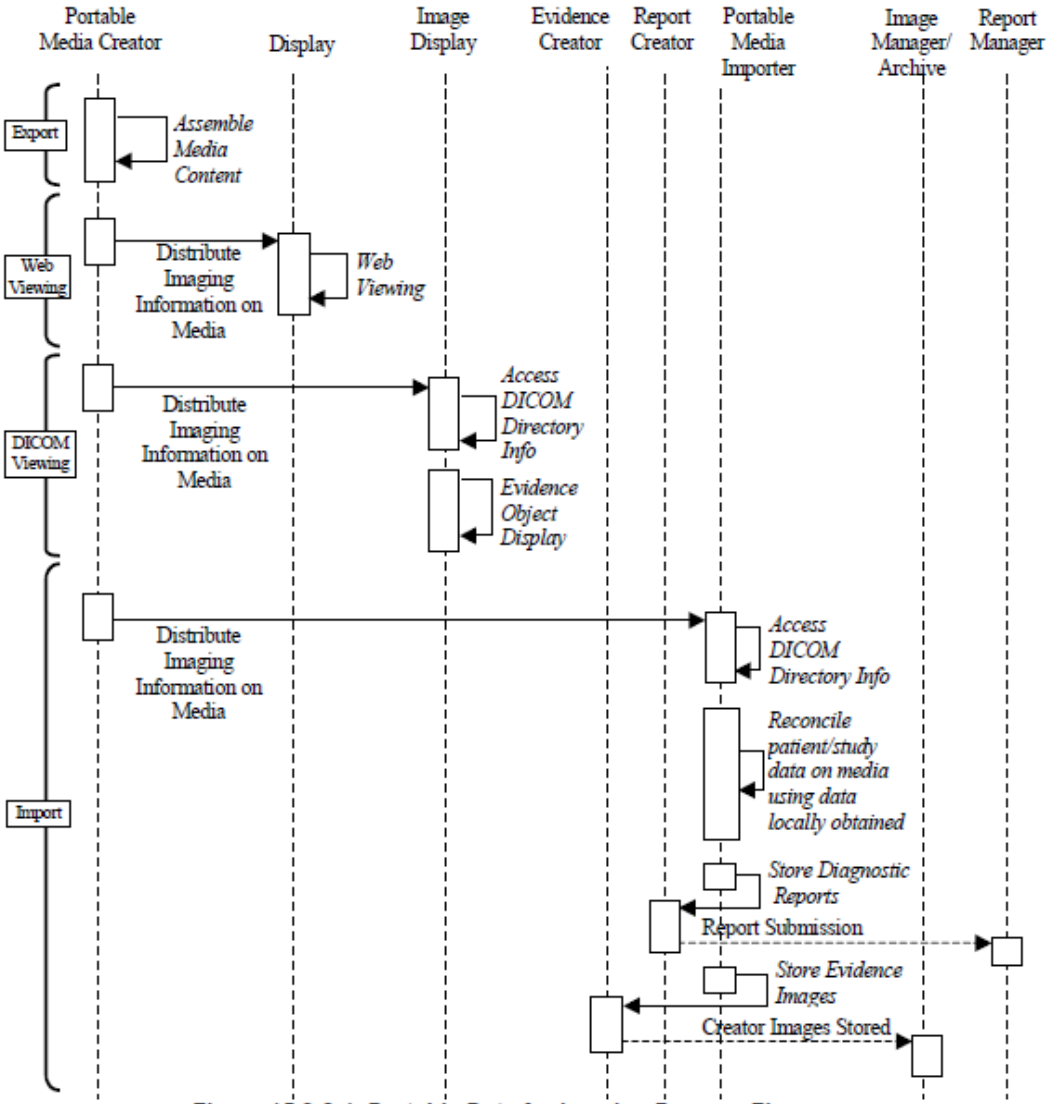


Figure 15.3-2-1. Portable Data for Imaging Process Flow

15.4 Media Content

The requirements on media content are intended to promote the reliable transfer of imaging data, including diagnostic reports, and to allow for the viewing of images and reports on general purpose computers.

The media content can be accessed via two "entry points" on the media: the DICOMDIR file for DICOM imaging information and optionally the INDEX.HTM file for web-viewable content. Created media are required to contain DICOM data and may optionally include web-viewable data derived from it. This web-viewable data, if present, shall faithfully preserve the clinical intent of the original DICOM information.

15.4.1 DICOM Content

The DICOM data shall be created by using the DICOM General Purpose Media Storage Application Profile. The DICOMDIR file shall reference all DICOM files stored on the media.

DICOM files shall not be placed in the root directory, but no constraints are placed on the name of directory that contains them.

15.4.2 Web Content Option

Portable Media Creators implementing the Web Content Option may also include web-viewable data on the media.

The web-viewable data shall be derived from the DICOM information as XHTML files and referenced JPEG images. The XHTML entry page (INDEX.HTM) shall allow access to all of this data. This enables end-users to access relevant media content using a generally available web browser. The INDEX.HTM file shall be placed in the root directory.

Note that the web-viewable data specified in this integration profile reflects the full set of the exported DICOM data or a subset considered at the time of creation to faithfully represent the patient's clinical condition. For example, if a DICOM Structured Report references only Key Images and a larger DICOM dataset, the web-viewable data derived from it may selectively include the report in XHTML format and only JPEG images derived from the DICOM Key Images.

15.4.3 Other Content

Viewing applications (for example a DICOM Media Viewer) may optionally be included on the media. Such viewers may have launch links included in the HTML. Including such viewers on the media is discouraged due to security issues discussed in the next section, as well as potential interoperability problems.

Additional data (e.g., a diagnostic report in non-DICOM format) may be also included on the media. Since the format of any such data is not specified by this profile, such data shall be placed in a separate directory on the media. If such data is referenced in the INDEX.HTM file, it shall be clearly indicated that this content was not generated in conformance with the IHE Radiology Technical Framework, and its reliable import has not been addressed.

15.5 Security and Privacy Aspects

Portable Media Creator actors shall ensure that no malicious software (viruses, etc.) is

present on created media.

The automatic launch of applications from media poses a risk that malicious software could be started and it is recommended that media reading actors not allow automatic launching. Portable Media Creators should therefore also avoid using automatic launching. This includes not automatically launching a DICOM media viewer that may be present on the media.

Furthermore, if a DICOM media viewer is present, security issues are minimized by:

- working under normal (restricted) user privileges and not requiring the user to work with administrator or root privileges and
- not needing software installed on the computer where the media is used.

Audit trails to track export/import/viewing activities are addressed in RAD TF-3: 4.34.1.1.1.15 and 4.34.1.1.1.H. Portable Media Creator and media reading actors that claim support of the Basic Security Integration Profile shall generate such audit trail entries.

Encryption of data and other access controls to media content are not addressed in this profile. Media created using this profile should be considered to be unlocked information (e.g., like paper records). Such media should be handled according to appropriate site policies (e.g., do not give a patient a disk containing data from other patients, do not leave disks where they can be taken by unauthorized persons, etc.). For many Use Cases it is not appropriate to place data from multiple patients on a single media for Security and Privacy Reasons.

4 IHE Transactions

This section continues the definition of each IHE transaction in detail, specifying the standards used, the information transferred, and the conditions under which the transaction is required or optional. **See Volume II, section 4 of the IHE Technical Framework for description of Transactions RAD-1 through RAD-31.**

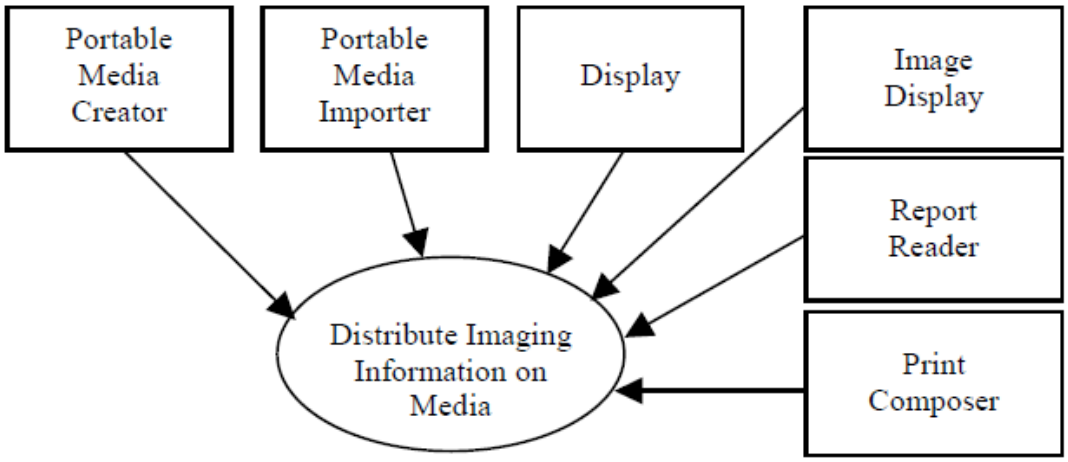
4.47 Distribute Imaging Information on Media

This section corresponds to Transaction RAD-47 of the IHE Technical Framework. Transaction RAD-47 is used by the Portable Media Creator and by media reading actors (Portable Media Importer, Image Display, Report Reader, Display and Print Composer).

4.47.1 Scope

In the Distribute Imaging Information on Media transaction the Portable Media Creator sends information to media reading actors by means of Interchange Media where it stores the information.

4.47.2 Use Case Roles



Actor: Portable Media Creator

Role: Assemble the media content and store it on the media to be distributed.

Actor: Portable Media Importer

Role: Read the DICOM content of distributed media in order to access information stored in the DICOMDIR file and its referenced instances (DICOM FSR) and perform import of media data.

Actor: Image Display

Role: Read the DICOM content of distributed media in order to access information stored in the *DICOMDIR* file (DICOM FSR) and display its referenced evidence objects.

Actor: Report Reader

Role: Read the DICOM content of distributed media in order to access information stored in the *DICOMDIR* file (DICOM FSR) and read its referenced diagnostic reports.

Actor: Print Composer

Role: Read the DICOM content of distributed media in order to access information stored in the *DICOMDIR* file (DICOM FSR) and send print data (images) to the Print Server.

Actor: Display (from ITI TF)

Role: Read the web-viewable content of distributed media in order to access information stored in the *INDEX.HTM* file and display its referenced data (XHTML files and JPEG images).

4.47.3 Referenced Standard

DICOM 2007 PS 3.10: Media Storage and File Format for Data Interchange

DICOM 2007 PS 3.11: Media Storage Application Profiles

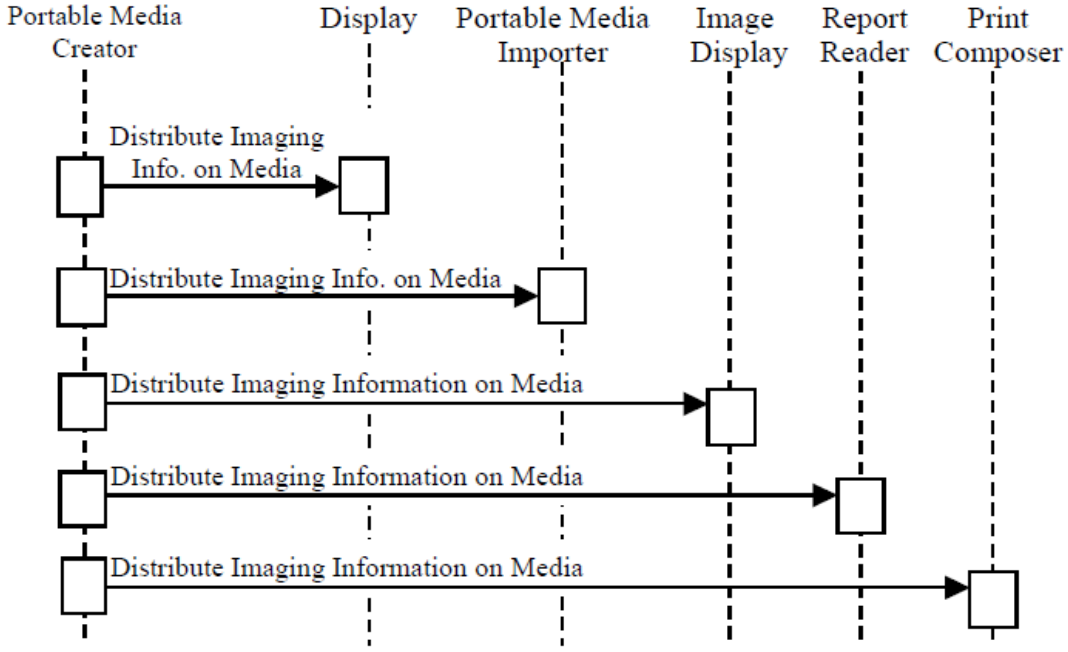
DICOM 2007 PS 3.12: Media Formats and Physical Media for Data Interchange

DICOM Supplement 80 (final text): DVD Media Application Profiles

XHTML™ 1.0 The Extensible HyperText Markup Language (Second Edition). A Reformulation of HTML 4 in XML 1.0. W3C Recommendation 26 January 2000, revised 1 August 2002. http://www.w3.org/TR/xhtml1.

XHTML™ Basic. W3C Recommendation 19 December 2000. http://www.w3.org/TR/xhtm-basic.

4.47.4 Interaction Diagram



4.47.4.1 Distribute Imaging Information on Media

This transaction consists of the interchange of information on media by way of the physical transport of the created media from the Portable Media Creator to a media-reading actor.

4.47.4.1.1 Trigger Events

The user at the Portable Media Creator wishes to transport information by the creation and transport of interchange media. The Portable Media Creator assembles the Interchange Media content and stores it on the media.

4.47.4.1.2 Message Semantics

The message semantics of this transaction are described in terms of content specifications for the media.

The Portable Media Creator shall be able to include all DICOM objects supported by the IHE actors with which it is grouped. If not grouped with any IHE actors, it shall be able to include all DICOM Storage objects listed in its DICOM Conformance Statement.

4.47.4.1.2.1 Media Filesystem and File Naming Restrictions

Since the DICOM content on the media is required to conform to the DICOM standard,

some of the requirements specified in PS 3.10, 3.11 and 3.12 are reiterated here for emphasis:

- Strict ISO 9660 Level 1 compliance
- No packet writing
- File and folder names referenced by the *DICOMDIR* file restricted to 8 characters, uppercase letters, digits and underscore only, with no extension

Specifically, it is not permitted to name DICOM files based on their SOP Instance UID, since that would exceed the 8 character limit and use the illegal period character, and it is not permitted to add a ".dcm" extension or similar. Filenames should not be in lower case, nor have lower case equivalent file names encoded as Joliet or Rockridge extensions to the ISO 9660 filesystem.
Refer to Appendix E of this supplement for a reference to common implementation misinterpretations and/or errors that are detrimental to interoperability.
Non-DICOM data is restricted to ISO 9660 Level 1 compliance, but without the restrictions on file extensions and characters imposed by DICOM; i.e. a 3 character extension is permitted.

4.47.4.1.2.2 Content Organization Overview

The following diagram illustrates the content organization principles (see Appendix F for examples):

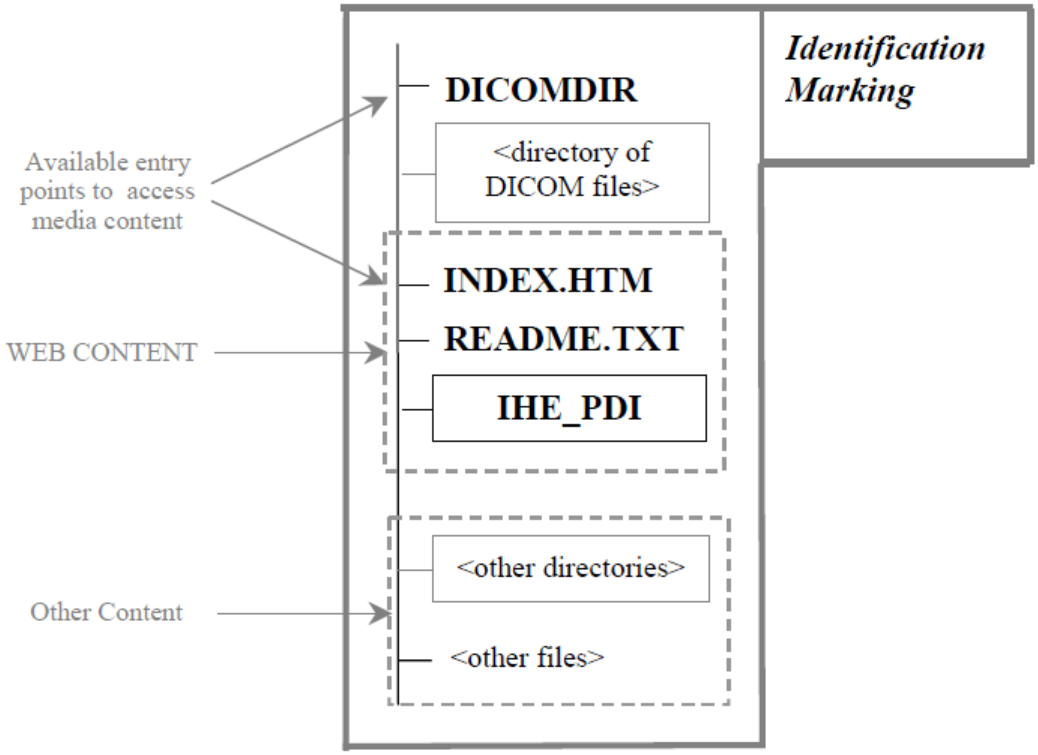


Figure 4.47.4.1.2.2-1. Media Content Organization

Description of the content to be contained in the media file system:

4.47.4.1.2.2.1 DICOM Content

The ***DICOMDIR*** file shall be located in the root directory and shall reference all DICOM instances contained in the media.
The DICOM instance files shall not be in the root directory or in the IHE_PDI sub-directory, instead they shall reside in a sub-directory whose name is not otherwise constrained.
It is recommended, though not required, to include the README.TXT file described below, even if the Web Content Option is not supported.

4.47.4.1.2.2.2 Web Content Option

Portable Media Creators implementing the Web Content option shall meet the following requirements:

- ***INDEX.HTM*** file located in the root directory, which shall portray the exact

content of the interchange media. The file shall present:

- An informative header containing:
  - Identification of the institution that created the interchange media
  - Optionally, a disclaimer statement about privacy/security from the institution that created the interchange media
- a link to an entry point for accessing the web content of the *IHE_PDI* directory
- a link to the *README.TXT* file
- a link to additional non-constrained data (if it exists) - See 4.47.4.1.2.2.3
- a manifest which lists the data that can be imported by a Portable Media Importer Actor. (i.e., all DICOM content on the media)
- a manifest which lists any patient-related data contained on the CD that cannot be imported (i.e., additional non-constrained content that doesn't have an importable DICOM equivalent on the media).
- a link to a launch point for a DICOM viewer, if present on the interchange media

Note: The file INDEX.HTM is required to present the content defined above to the user. This does not imply that the information must necessarily be contained in INDEX.HTM. Instead, INDEX.HTM might also open a frame set consisting of additional XHTML files that in total contains the information specified above.

- ***README.TXT*** file located in the root directory, that shall contain:
  - Contact information regarding the Institution that created the media.
  - Information regarding the Application that created the media.
    - Name of the product application and software version
    - Contact information of the vendor of the application that created the media
  - General information about the overall organization of the interchange media. This is not intended to be specific to the content stored on this instance of interchange media, which if necessary should be placed in the *INDEX.HTM* file.
  - Information regarding the Media Viewer application (if a Media Viewer is contained)
    - Operating system(s) supported
    - Name of the product application and software version
    - Contact information of vendor that provided the Media Viewer

application
- Disclaimer statement about the intended usage of the application
- List of minimum requirements
- Additional information regarding the usage of the application

Note that generally the README.TXT file is independent of the clinical content of the media, i.e. the same README.TXT may be included on all media created by that application at that institution.
It is recommended that information is included in the README.TXT file about web browsers (including version number) that are known to be capable of displaying the web content as intended.

- ***IHE_PDI*** directory located in the root directory of the interchange media which shall contain:
  - Web-viewable objects in XHTML, JPEG, PNG and/or GIF derived from the DICOM encoded objects or used for web page navigation.
  - The web content shall faithfully represent the patient's clinical condition.
  - It is not allowed to place any other data in the *IHE_PDI* directory.
  - It is allowed to have sub-directories within the *IHE_PDI* directory

Note that these are IHE requirements (not DICOM requirements) that are intended to facilitate the overall organization of the media and make easier the access to the *INDEX.HTM* file, especially for non-expert users like patients and referring physicians.
Note: There is a recognized need for cine/video data, however a standardized method (format) has not yet been identified for endorsement by IHE and inclusion in this transaction.

4.47.4.1.2.2.3 Optional Content

It is permitted to place other optional data on the media outside the *IHE_PDI* directory, but any additional content shall take into account all constraints listed above.
Furthermore any additional directory cannot begin with “IHE”.
Additional files (files other than mandatory files) in the root directory are not expressly prohibited however their inclusion is discouraged.
Note that it cannot be assumed that any automatically launching application will run on the receiving device.

4.47.4.1.2.2.3.1 DICOM Media Viewer

If a DICOM media viewer is present on the media, it is recommended that:

- the media viewer be capable of correctly rendering all DICOM objects stored on the medium.
- a user manual in PDF format be included on the medium, in the root directory.
- a short manual in hardcopy be provided within the CD jewel case.

4.47.4.1.2.2.4 Media Identification

The Portable Media Creator actor shall support a user in adding human-readable identification information on the outside of the physical medium. The method of media marking is outside the scope of this integration profile.

It is recommended that the Patient Name, patient ID, birthdate, media creation date, the study dates for the studies on the medium and the name of the originating institution be marked on the medium. It is also recommended that the type of content ("DICOM ONLY" or "DICOM PLUS WEB") be marked on the medium.

4.47.4.1.2.3 Content Organization Detail

4.47.4.1.2.3.1 DICOM Content

The DICOM portion of the media content is defined by the current DICOM standard. It is required that created file-sets be correctly formatted in order to grant maximum interoperability.

All DICOM data shall be referenced by the *DICOMDIR* file.

In order to assure interoperable use of the created media, a "widely-used" general purpose DICOM Media Application Profile is required. The Portable Media Creator, Portable Media Importer, Image Display, Report Reader and Print Composer shall use the STD-GEN-CD Media Storage Application Profile to interchange DICOM information on interchange media.

The Portable Media Creator is not required to be able to create media containing data from multiple patients. However, all media reading actors shall be able to import media containing multiple patients' data.

While the Portable Media Creator is not required to correct DICOM SOP instances from a source that incorrectly encodes the DICOM data, it is expected that the DICOM Media Creator will store the DICOM files in Explicit VR Little Endian. The DICOMDIR, whose content is entirely the responsibility of the Portable Media Creator, shall be correctly encoded regardless of the correctness of any referenced SOP Instances.

The Portable Media Creator may be requested to include DICOM SOP Instances that

do not contain sufficient information to encode mandatory DICOMDIR information. For example, Patient ID and Study ID are Type 2 and may be zero length in image SOP Instances, but are Type 1 in the Patient and Study Directory Records. The Portable Media Creator is required to synthesize appropriate values for all such mandatory attributes. No specific guidance is given as to from whence appropriate values should be obtained or what default values are appropriate, except that different patients, studies, and series must remain distinct (e.g., two different Studies with differing Study Instance UIDs shall not be assigned the same synthesized Study ID).

4.47.4.1.2.3.1.1 DICOM Instances Content

There are no additional requirements specified here on the Attributes contained within DICOM Instances on the media.

If the Portable Media Creator Actor is grouped with an Acquisition Modality (or other) Actor within the Scheduled Workflow Integration Profile, then the attributes may effectively be constrained beyond the normative requirements of the DICOM standard. For example certain attribute values in the Modality Worklist query shall be included. However, since such grouping is not required under this profile, actors receiving created media such as the Portable Media Importer, Image Display, Report Reader and Print Composer may not assume that the DICOM Instance Attributes are constrained beyond the definitions of the IODs in the DICOM Standard.

The instances on the Interchange Media generated by a Portable Media Creator shall all be DICOM Composite IODs. Therefore the Interchange Media shall not contain instances from the following SOP Classes:

- Detached Patient Management SOP Class
- Detached Study Management SOP Class
- Detached Visit Management SOP Class
- Study Component Management SOP Class
- Modality Performed Procedure Step SOP Class
- Detached Result Management SOP Class
- Detached Interpretation Management SOP Class
- Stored Print Storage SOP Class

4.47.4.1.2.3.1.2 DICOMDIR Directory Content

There are no additional DICOMDIR keys required beyond those required by the DICOM STD-GEN-CD specification.

No private elements shall be included in the standard directory records and no private directory records shall be present.
The following types of Directory shall not be used in the Basic Directory object (DICOMDIR File):

- VISIT,
- RESULTS,
- INTERPRETATION,
- STUDY COMPONENT,
- STORED PRINT
- TOPIC
- PRIVATE

The PATIENT, STUDY, SERIES Directory Records shall follow the following rules:

- Only one Directory Record per Patient ID shall be present in the DICOMDIR.
- Only one STUDY Directory Record per Study Instance UID shall be present in the DICOMDIR; this implies that a study belongs to a single patient.

Only one SERIES Directory Record per Series Instance UID shall be present in the DICOMDIR; this implies that a series belongs to a single study.

- Only one composite instance level Directory Record shall be present per SOP Instance UID; this implies that an instance belongs to only a single series.
- Only one HL7 STRUC DOC Directory Record shall be present per SOP Instance UID; this implies that an instance belongs to only a single Patient.

- Only one HANGING PROTOCOL Directory Record shall be present per SOP Instance UID

Users should review the supported Media Storage SOP Classes in the Conformance Statements of media creators and readers to ensure interoperability in the interchange of media objects.

4.47.4.1.2.3.1.3 DICOM Report Content

It is highly recommended to place diagnostic reports on the media.
The Portable Media Creator actor, if grouped with a Report Creator actor, shall support the ability to create a diagnostic imaging report. A Basic Text DICOM SR, according

to a proper subset of the Simple Image Report Pattern as defined by the SINR Integration profile, can be created and this kind of diagnostic report can be imported by a Portable Media Importer.
Additional optional diagnostic reports in non-DICOM formats (such as HL7 CDA) are not defined by this transaction and may be placed on the media without the need to create DICOM SRs, but they will be non-importable data.
Note: This requirement may be met with other DICOM SR SOP Classes that are used for diagnostic or therapeutic reports. For the most basic radiology report, a simple pattern with one or more sections including a paragraph of text meets this requirement. Image references do not have to be included, but may be if so desired.

4.47.4.1.2.3.2 Web Content Option

Portable Media Creators claiming the Web Content option shall meet the following requirements:
End-users should be able to access information at a minimum using a web browser to view content on media. In order to grant maximum interoperability using the stored XHTML files, they shall be formatted according to the XHTML Basic and W3C HTML Compatibility Guidelines provided in Appendix C of the W3C XHTML 1.0 Recommendation.
The web-viewable data that is generated by Portable Media Creators claiming the Web Content option shall:

- contain the web representation of a subset of the media's DICOM information, using only XHTML files, JPEG referenced images, and PNG and/or GIF files used for navigation,
- contain hyperlinks within XHTML files which contain only lowercase letters to promote interoperability across O/S Platforms,
- reside in the *IHE_PDI*, while the corresponding DICOM data from which it is derived is located in a different sub-directory (see 4.47.4.1.2.2.1), and
- be completely referenced in the *INDEX.HTM* file

The web-viewable data included shall be a set or subset that was considered at the time of creation to faithfully represent the patient's clinical condition.
If the Portable Media Creator supports Presentation States, it shall have the capability to apply them to the relevant images when including web-viewable content. The user of the application may choose not to make use of this capability.

The constraints placed by DICOM on the ISO 9660 file system are not required for web-viewable content, i.e. a 3-character extension is permitted.
To ensure interoperability, JPEG means a file with a JFIF header and encoded using the sequential Huffman DCT 8bit per component process (baseline), and the progressive variant thereof.
To ensure interoperability the use of XHTML shall be limited to static and restricted forms of dynamic web content. At this time Dynamic Web Content such as DHTML, Cascading Style Sheets and most Scripting Languages are explicitly prohibited as no single established Standard exists to ensure interoperability between web browsers. The use of JavaScript is explicitly permitted, recognizing that there may be issues with different browsers. Portable Media Creators should make every effort to use portable constructs or use JavaScript that works with or adapts to all known portable browsers ; further, the failure of JavaScripts should not make the resulting web pages unusable.
Additional optional web-viewable content not derived from DICOM objects may be stored on the media, but not in the *IHE_PDI* directory.

4.47.4.1.3 Expected Actions

The receiving/reading actors read the patient's data from the media and act upon it as specified below. The receiving actor shall document which DICOM objects it supports in its Conformance Statement. If a SOP Class on the media is not supported, the actor shall present the user with a summary of the data that could not be acted upon, containing the Patient Name(s) and ID(s), Study ID(s), Study Date(s), Study and Series Description(s) and Modality as obtained (if present) from the *DICOMDIR* file.
The automatic launching of applications is not expressly prohibited on media interchanged within this profile; its use is discouraged, however.
To facilitate avoidance of malicious software, receiving actors (Portable Media Importer, Image Display, Report Reader, Print composer and Display) are not required to launch automatically running applications present on media.

4.47.4.1.3.2 Image Display

The Image Display reads the DICOM image data from the media and provides the user with the ability to view all studies (that it supports) contained on the media. GSPS objects and Key Image Notes are read from the media and applied if the Consistent Presentation of Images and the Key Image Notes IHE Integration Profiles are supported. The Image Display actor may optionally be grouped with other actors which view other evidence objects.

4.47.4.1.3.3 Report Reader

The Report Reader reads the DICOM SR Reports from the media and may process them (based on the SR object classes it supports). At a minimum, it provides the user with the ability to view all reports per the DICOM SR SCP requirements.

4.47.4.1.3.4 Portable Media Importer

The Portable Media Importer reads DICOM data from the media. Together with the actor with which it is grouped (see vol. 1), it shall be able to perform key attribute reconciliation. Reconciliation may not be required in all cases (e.g., within the same importing institution/enterprise). Refer to Table 4.47.4-1 for key attributes to be reconciled. Import Reconciliation Workflow provides a workflow to reconcile key attributes (See Section RAD-TF 1:3.59). Note that the Referenced Study Sequence and Requested Attributes Sequence are removed for consistency with behavior of the unscheduled cases in SWF and PIR.

The grouped actors provide the capability of storing the supported DICOM objects to an Image Manager/ Image Archive (for image objects like Images, Presentation States, Key Image Notes, Evidence Documents), or to a Report Repository (for Diagnostic Reports).

Table 4.47.4-1 Media instances - Key attributes to be reconciled

Attribute from Media	Updating action
Patient Name	Replace with value from ADT (See note 1)
Patient ID	Replace with value from ADT (See note 1)
Patient's Birth Date	Replace with value from ADT (See note 1)
Patient's Sex	Replace with value from ADT (See note 1)
Study Instance UID	Remains unchanged
Series Instance UID	Remains unchanged
SOP Instance UID	Remains unchanged
Workflow-related Identifying Attributes (e.g. Order, Requested Procedure, Scheduled and Performed IDs and UIDs).	Values from such identifying attributes of media information • remain unchanged, • are replaced with a value from the local environment, or • are removed (zero length value). The exact method of reconciliation depends on the importing institution's procedures, and goes beyond the IHE scope.
Descriptive performed procedure information (this is information that pertains to the manner in which the information was created (e.g. acquisition context) or it may be payload of the instance (e.g. image structure, document content))	Remains unchanged (see Note 2)

Note 1: The manner in which the Portable Media Importer receives the ADT value is beyond the scope of this profile.

Note 2: Handling of Coded information is beyond the scope of this Integration Profile.

4.47.4.1.3.5 Print Composer

The Print Composer reads the DICOM image data from the media and provides a means to print it.

4.47.4.1.3.6 Display

The Display actor (defined in the IT Infrastructure TF) reads the web-viewable information from the media and displays it. Note that the web-viewable content will only be present if the Portable Media Creator involved supports the Web Content Option.

Appendix E: DICOM Media Interchange – Critical DICOM Compatibility Tips

This appendix presents a number of compatibility issues that result from not following the DICOM Media Interchange standard (PS 3.10, PS 3.11 and PS 3.12). This appendix is simply intended to be a reminder for the most common DICOM issues that have resulted in the past in incompatibilities between file set creators and readers.
This list shall not be interpreted, as being the only DICOM requirements that implementers should pay attention to. DICOM has proven to be a very effective and thorough specification that implementers of this IHE profile shall be familiar with.

1. The CD Media shall be formatted according to ISO 9660 Level 1. (Extensions such as Joliet or Rock Ridge are not forbidden by DICOM and hence are permitted by the PDI profile., nor a A UDF file system are is not allowed unless an ISO 9660 Level 1 Filesystem is also present). Such extensions may be necessary to encode non-DICOM content on the media, such as long filenames for viewing software. Such extensions may result in ISO 9660 Level 1 uppercase filenames being presented to application software as lowercase or mixed case depending on the operating system's mount behavior; accordingly, all Portable Media Displays and Portable Media Importers shall be case insensitive in this respect.
2. The *DICOMDIR* file shall be at the root directory of the Interchange Media
3. All DICOM file names (DICOM files as well as non-DICOM Files) shall contain only uppercase letters, numeric digits and the underscore character, and. tThe file name size without extensions shall not exceed 8 characters.
4. All Directory names in DICOM paths shall contain only uppercase characters, numeric digits and the underscore character. Directory names shall not contain extensions.
5. Non-DICOM files shall notmay have extensions with more than 3 characters (ISO 9660 Level 1).
6. DICOM files shall have no extension.
7. DICOM files shall have an ISO 9660 version of 1, which may be displayed by some operating systems as a ".;1" at the end. However, the ".;1" should not be included in the name of the file itself.
8. The version number of the file name shall not be included in the reference data element in the DICOMDIR.
9. Only 8 levels of Directories are allowed, including the root directory (i.e. there

may be up to 7 levels of sub-directories below the root).

10. Objects in DICOM files shall be stored in Explicit VR Little Endian (not Implicit)
11. DICOM File Meta-Information shall be in Explicit VR Little Endian (not Implicit)
12. File Meta Information Version (0002,0001) shall contain a two byte OB value consisting of a 0x00 byte, followed by 0x01 byte, and not the value 0x0001 encoded as a little endian 16 bit short value, which would be the other way around.
13. The file meta information shall include the Media Storage SOP Class UID (0002,0002) data element, and its value shall be equal to the SOP Class UID data element in the data set.
14. The file meta information shall include the Media Storage SOP Instance UID (0002,0003) data element, and its value shall be equal to the SOP Instance UID data element in the data set.
15. No private elements shall be included in the file meta information.
16. The file meta information header shall contain an attribute (0002,0000) Group Length with a correct value as specified in DICOM PS 3.10.
17. The physical format of the DICOM CD-R discs shall comply with the application definitions within ISO/IEC 10149 Part II as specified in PS3.12. This allows discs to be written with
    - Mode 1 sectors or
    - Mode 2, Form 1 sectors with CD-ROM-XA File Number = 0, Channel Number = 0 and Coding Information Byte = 0.

Appendix F: Example Created Media Instance Content

Example F-1. Media containing a DICOM CT imaging study, a DICOM Presentation States and a DICOM Structured Report. The creator supports the Web Content Option and includes web-viewable data derived from DICOM data on the media. Also a DICOM Viewer is included on the media.

Content element(s)	Description
Identification Marking	Marker with content per 4.47.4.1.2.2: patient name creation date name of the institution that created the media
/README.TXT	File with content per 4.47.4.1.2.2
/INDEX.HTM	File with content per 4.47.4.1.2.2: media type: "DICOM PLUS WEB" links to XHTML report and to another page (THUMBS.HTM) with thumbnails that link the full resolution JPEG images link to a launch point for the DICOM viewer in the VIEWERS directory link to the list of importable data
/DICOMDIR	DICOM Directory file referencing all DICOM instances: all DICOM images the PS object the SR object
/ DICOM/ /DICOM /12296 /DICOM /12297 . . . /DICOM /NNNNN /DICOM /98732 /DICOM /12312 /IHE_PDI /REPORT.HTM /IHE_PDI /THUMBS.HTM /IHE_PDI /T_12296.JPG /IHE_PDI /T_12297.JPG /IHE_PDI /I_12296.JPG /IHE_PDI /I_12297.JPG	Directory with content per 4.47.4.1.2.2: Image object 1 Image object 2 . . . Image object N DICOM Presentation State object Basic Text DICOM Structured Report object XHTML report navigation page derived from DICOM data that displays T_12296.JPG and T_12297.JPG thumbnail of Image object 1 thumbnail of Image object 2
	full resolution JPEG image for view within browser full resolution JPEG image for view within browser
/VIEWERS/ /VIEWERS/VIEWER.EXE	Optional directory: executable viewer

Example F-2. Media containing a DICOM US imaging study and a DICOM SR diagnostic report. The creator does not support the Web Content Option but chose to optionally include the README.TXT file. No web-viewable data derived from DICOM data is included on the media.

Content element(s)	Description
Identification Marking	**Marker with content per 4.47.4.1.2.2:** **patient name** **creation date** name of the institution that created the media **media type: "DICOM ONLY"**
/README.TXT	**File with content per 4.47.4.1.2.2**
/DICOMDIR	DICOM Directory file referencing all DICOM instances: all DICOM images the SR object
/DICOM/ **/DICOM**/78567856 **/DICOM**/78567857 . . . **/DICOM**/NNNNNNN **/DICOM**/12343412	**Directory with content per 4.47.4.1.2.2:** **Image object 1** **Image object 2** **.** . . **Image object N** **Basic Text DICOM Structured Report object**